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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,852

12/12/2005

Steven Paul Boneham

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09/07/2007

WOMBLE CARLYLE SANDRIDGE & RICE, PLLC

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ATLANTA, GA 30357-0037

EXAMINER

KINSEY, NICOLE

ART UNIT

PAPER NUMBER

1648

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DELIVERY MODE

09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,852

Applicant(s)

BONEHAM ET AL.

Examiner

Nicole E. Kinsey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-10,15,23,25,26 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-10 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/17/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: There are numerous amino acid and nucleotide sequences throughout the specification without an appropriate sequence identifier (i.e., SEQ ID NO:X). Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 6). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 7 is objected to because of the following informalities: Claim 7 recites "a linear epitope which recognizes the HIV-1 neutralizing antibody." Epitopes do not recognize antibodies. Appropriate correction is required.

Claims 23 and 31 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 23 and 31 not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, 8, 10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Binley et al. (Journal of Virology, 2000, 74(2):627-643).

The claims are drawn to a molecule that contains a trimeric presentation of a peptide which is recognized by an HIV-1 neutralizing antibody selected from the group consisting of 2F5, IgGi-b12, 4E10 and Z13, which molecule is stabilized by inter-chain disulfide bridging of the peptides. The molecule may be a homotrimer of a polypeptide chain which polypeptide chain contains a spacer portion, a linear epitope recognized by the HIV-1 neutralizing antibody, a multimerization portion and, optionally, a carrier portion, wherein the polypeptide chain has a molecular weight no more than 30 kDa. The molecule may also comprise a first polypeptide chain, which contains a linear epitope recognized by the HIV-1 neutralizing antibody and a second polypeptide chain, which partially occludes the linear epitope on the first polypeptide chain.

Binley et al. discloses a gp140 polypeptide of HIV (SOS gp140) that forms trimers via the multimerization portion of gp41 and that is stabilized with inter-chain

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disulfide bridges between peptides of the molecule (see, for example Figure 1D). The trimer mimics the structure of the virion-associated gp120-gp41 complex and has epitopes recognized by neutralizing antibodies such as IgG1b12 (see page 632) and 2F5 (see page 635). The molecule further contains portions that occlude neutralizing epitopes in the trimer (see page 640, the CD4-induced neutralizing epitopes are occluded by V1/V2 and V3 loop structures and gp120 components of the trimer).

Claims 1, 3, 5, 8, 10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (U.S. Patent Application No. 2005/0089526).

Moore et al. discloses a gp140 polypeptide of HIV (SOS gp140) that forms trimers via the multimerization portion of gp41 and that is stabilized with inter-chain disulfide bridges between peptides of the molecule. The trimer mimics the structure of the virion-associated gp120-gp41 complex and has epitopes recognized by neutralizing antibodies such as IgG1b12 (see paragraphs [0323]-[0329] and 2F5 (see, for example, paragraph [0329])). The molecule further contains portions that occlude neutralizing epitopes in the trimer (see, for example, paragraph [0335]).

Claims 1, 3, 4 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lu et al. (U.S. Patent No. 7,179,468).

Lu et al. discloses a homotrimer comprising HIV gp41 peptides. The trimer also comprises disulfide bonds (see, for example, Figures 1 and 2). The trimer contains epitopes recognized by the neutralizing antibody 2F5 (see Table I and col. 21, lines 36-

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50), and the trimer can be composed of smaller fragments of gp41, such as amino acids 536-666, that are less than 30 kDa (see Figure 2 and col. 7, lines 11-30). Lu et al. also teaches that carriers can be link to the monomer units directly or via a spacer molecule (see col. 11, line 59 to col. 12, line 8).

Claims 1, 3, 5, 7-10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sodroski et al. (U.S. Patent No. 6,911,205).

Sodroski et al. discloses soluble trimers of processed/cleaved HIV gp140 monomers or unprocessed/uncleaved gp140 monomers used to elicit an immune response (see Summary and Figures 6A-6C). The trimers contain epitopes that are recognized by neutralizing antibodies such as IgG1b12 (see col. 26, line 51 to col. 27, line 23) and contain a multimerization portion (see col. 10, lines 47-67). The monomer peptides further contain disulfide bridges to stabilize neutralization epitopes specific for the trimers (see col. 12, lines 27-35). The individual monomers can mask (i.e., occlude) such natural epitopes by burying them when a trimer is formed (see col. 12, lines 35-38).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is

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(571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E. Kinsey, Ph.D.
Examiner
Art Unit 1648

/nk/

/Stacy B. Chen/ 8-30-2007
Primary Examiner, TC1600